

SPECIFICATION AMENDMENTS

Please amend page 2, line 29 to page 3, line 10 to read as follows:

Sodium alginate is used in cases of gastrointestinal reflux, heartburn and esophagitis. In the Patent numbered EP-A-0059221, the protective effect of alginic acid and its water soluble salts in gastrointestinal channel have been disclosed. In the patent with PCT publication No. of WO 01/66119, the compositions which cover the sachet formulations of alginic acid and sodium alginate are disclosed and these do not cover the combination of alendronate microparticles with sodium alginate and alginic acid that are coated with polymers resistant to salivary pH. It has been cited that sodium alginate disclosed in the patent with No. of 99/04773, may be used as an ingredient in preparation of pharmaceutical dosage forms but the addition of sodium alginate in therapeutic amounts to the formulation to compensate the esophageal reflux and gastric side effects of alendronate has not been cited. Sodium alginate or alginic acid may be obtained commercially from FMC or Monsanto (for example: ~~Protanal~~ PROTANAL[®] LFR 5/60 or ~~Munucol~~ MANUCOLR[®] LB).

Please amend page 3, lines 19 to 29 as follows:

Side effects occur with alendronate depending on its irritation of esophagus. To prevent this irritation one of the approaches of this invention is to prevent the contact of alendronate particles with esophagus. To ensure this, alendronate particles are coated with a polymer resistant to salivary pH. Microparticles of alendronate may be prepared by extrusion-rolling, vessel or liquidized bed procedures. The prepared particles are coated with a polymer resistant to salivary pH in a vessel or liquidized bed. For the coating purposes polymers such as aminoalkylmethacrylate copolymers and polyvinyl acetate diethylaminoacetate polymers that are insoluble (neutral pH) in saliva, but soluble in gastric pH may be used. Eudragit-E EUDRAGIT® E (polymethacrylates, polyvinyl acetate diethylaminoacetate and poly butyl methacrylate / 2-dimethylamino-ethyl methacrylate / methyl methacrylate copolymers) which [[that]] is commercially produced in Röhm Pharma can be used in the coating.

Please amend page 5, lines 11 to 18 to read as follows:

By the use of the spray coating procedure, alendronate is aggregated with polyvinylpyrrolidone dissolved in ethanol. The aggregated particles are coated with the following mixture.

Eudragit <u>EUDRAGIT</u> ® E100	10 mg - 280 mg
Ethanol	50 mg - 400 mg
Acetone	50 mg - 400 mg
Colloidal silica	2 mg - 15 mg

EUDRAGIT ® E100 means poly (butyl methacrylate, 2-dimethylaminoethyl methacrylate, and methyl methacrylate) in a ratio of 1:2:1.

Please amend page 5, lines 25 to 29 to read as follows:

Coated microparticles equivalent to 10 mg alendronic acid 26 mg

Sucrose 4648.9 mg

Sodium alginate (~~Protanal~~ PROTANAL® LFR 5/60) 300 mg

Saccharine sodium 0.1 mg

PEG 6000 (lubricant) 25 mg